



## MODERATE ALCOHOL AND CARDIOVASCULAR HEALTH TRIAL (MACH15)

Model Informed Consent Form to Participate in Research

First Name Last Name, Degree, Principal Investigator

### INTRODUCTION

You are invited to be in a research study called the Moderate Alcohol and Cardiovascular Health Trial (MACH15). The principal investigator listed above is in charge of the study at (clinical site name). Other people, such as study coordinators or research nurses, may help or act for him/her.

You are being asked to take part in MACH15 because you are age 50 or older, drink alcohol once in a while, and have above-average risk for heart disease. Your risk of heart disease is determined by several things, including smoking history, health history, and levels of lipids in the blood.

Taking part in a research study is voluntary. Please read this form carefully and take your time to decide. Ask the investigator or the study staff to answer any questions you may have. You may also discuss the study with your friends, family, and doctor.

The study has been approved by [INSERT SITE SPECIFIC INFORMATION HERE]

### WHY IS THIS STUDY BEING DONE?

There is a lot of debate on the health effects of moderate (no more than 1-2 alcoholic beverages each day) alcohol use. Many studies found that adults who reported drinking alcohol in moderation tended to develop heart disease and diabetes less often than adults who drank no alcohol. However, other studies found opposite results or showed no relationship between drinking alcohol and these diseases.

We are conducting this study because we want to examine the relationship between moderate drinking of alcohol and risk of heart disease and diabetes.

We hope to accomplish these goals by enrolling people with known risk factors for heart disease. For about 6 years, you will be asked to either drink one serving of alcohol each day or to abstain from drinking alcohol.

### HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 7,800 participants in many cities around the world will take part in this study. At each site, there will be approximately 500 participants.



## WHAT IS INVOLVED IN THE STUDY?

MACH15 will have two study groups: the alcohol group and the non-alcohol group. Participants in MACH15 will be assigned by chance (like flipping a coin) to either drink one serving of alcohol each day or to abstain from drinking alcohol. You will have an equal chance of being placed in either group and should be willing to be placed in either group.

If you are assigned to the alcohol group, you will be asked to drink **one** serving of wine, beer, or spirits every day (7 drinks/week). One serving of alcohol per day is equivalent to the standard serving size of approximately 5 ounces of wine, 12 ounces of beer, or 1.5 ounces of spirits. You will be advised to drink this beverage after activities that require dexterity are over for the day. Please consume your alcoholic beverage at a time when you will not be driving or operating heavy machinery. If you are assigned to the non-alcohol group, you will be asked not to drink alcohol. You will be asked to follow your group assignment for the duration of the study, about 6 years.

Your participation will involve as many as 10 visits and 18 telephone calls. In addition, we will contact you throughout the study to ask you questions about your alcohol use using text messages, emails or through online reporting. Some of the procedures in this study will be repeated several times during the visits and telephone calls.

The study involves the following tests and procedures:

**Interviews regarding health and alcohol use:** You will be asked questions about your alcohol use several times during the study. This will be during study visits, phone calls, via text messages, emails, or using the internet. You will be asked about your medical history, along with a listing of any medications you are taking. Throughout the study you will be asked to report any medical events that have happened to you, such as new diagnoses or hospitalizations.

You will be asked for your contact information, as well as the contact information of a family member or friend who can be contacted in case we cannot reach you. This person may also provide information and answer questions for you if you are unable to answer for yourself or can provide more information about your health if needed. If you are not able to provide contact information for at least one family member or friend, you will not be able to participate in this study.

**Physical measures:** Measurements of body weight, height, waist circumference, pulse and blood pressure will be conducted.

**Blood sampling:** Blood will be drawn from a vein in your arm to measure your blood sugar, cholesterol, liver, and kidney function. At some visits you may need to be fasting. This means that approximately eight (8) hours before your scheduled visit, you are not allowed to eat or drink anything except water.



**Blood, urine and hair collection for storage and future research:** If you consent specifically, a blood, urine, and hair sample will be collected and may be used in future research. Future research may provide additional information that will be helpful in understanding heart disease and other diseases. If you do not want your blood, urine, or hair sample to be stored and used for future research, you can still take part in the MACH15 trial.

**Questionnaires:** You will be asked to complete several questionnaires throughout the study. These questionnaires will ask about your smoking status, nicotine dependence, mobility, self-care, pain, discomfort, depression, medications, and updates about hospitalizations and medical events that happen to you. You will also be asked to complete a few online questionnaires about other health matters, for example, your physical activity and the types of foods that you eat.

## WHAT HAPPENS AT EACH VISIT?

**Screening Visit:** Your first study visit is called a “screening” visit. After signing the informed consent form, we will perform some tests and ask questions to determine if you qualify for the study. Your blood pressure, medical history, current medications and demographic information will be reviewed. Blood will be drawn from a vein in your arm (approximately 2 teaspoons). In addition, you will be asked to provide your contact information as well as the contact information of someone close to you.

### Screening period – abstain from alcohol

Following the screening visit, you will be asked to abstain from drinking alcohol for two weeks. This will help you understand your ability and willingness to comply with your study assignment, if you are assigned to the non-alcohol group. You will receive a telephone call from one of our study staff at the end of the wash-out period and you will be asked if you had abstained from drinking alcohol as directed. If you were unable to do so, you are not eligible to participate in the study.

**Visit 1:** At this visit (baseline visit), your blood pressure, height, weight, and waist circumference will be measured. You will be asked questions about your demographics, health, smoking history, medications, hospitalizations, medical events, and quality of life. You will also have blood drawn from a vein in your arm (approximately 10 teaspoons) and be asked to provide a hair and urine sample. You will also be asked to complete online questionnaires about your physical activity and the foods that you eat.

If you are eligible for the study, you will be randomly assigned to either drink one alcoholic beverage each day or to abstain from drinking alcohol each day. You will have an equal chance of being placed in either group.

You will receive health coaching, be informed on the drinking guidelines and advised on how to integrate these in your daily life. Depending on which group you have been assigned to, you will also be provided with information on how to obtain a supply of an alcoholic beverage.



**Visit 2 and 3:** These visits will be 3 and 6 months after your baseline visit. At these visits, your blood pressure will be measured and you will be asked about your health, hospitalizations, medical events, and alcohol use. You will have blood drawn (approximately 3 teaspoons) from a vein in your arm.

**Annual Visits:** These visits will be 12 months after your baseline visit and once a year thereafter. At these visits, your blood pressure, weight and waist circumference will be measured. You will be asked questions about your health, demographics, alcohol use, medications, hospitalizations, medical events, and quality of life. You will have blood drawn (approximately 3 teaspoons) from a vein in your arm. You will be asked to complete online questionnaires about your physical activity and the types of foods you eat. You will also be asked to confirm your contact information as well as the contact information of someone close to you.

**Phone calls:** You will receive a telephone call 2 weeks, 4 weeks, and 9 months after your baseline visit. Then phone calls will occur 3, 6, and 9 months after each annual visit. The purpose of these calls is to ask questions about your health, hospitalizations, medical events, and alcohol use, and to offer study support between visits to the clinic. If you choose, you may also receive phone calls to ask questions about your alcohol consumption in the previous 24 hours.

**Automated contacts:** If you agree, you will be contacted (smart phone application, text message, or email) at least 7-10 times each quarter to provide information on the amount and type of alcohol that was used in the previous 24 hours. You can choose which type of message you would like to receive by contacting the staff at your clinical site. Below we provide some additional information about each type of message.

*Mobile Application:* If you choose to use the mobile application, you agree to install a mobile application on your mobile phone through which a company hired to help with the study will send you messages that remind you to provide information about your alcohol consumption during the past 24 hours. To discontinue receiving these messages, please contact your study site.

*Text Messages:* If you choose to receive text messages, a company hired to help with the study will send you automated text messages reminding you to provide information on your alcohol consumption during the past 24 hours. These text messages will be sent to the phone number that you provide to your study site. Message rates differ from carrier to carrier, so please contact your wireless phone provider to inquire about the details of your plan. To discontinue receiving these messages, please contact your study site.

*Email:* If you choose to receive emails, a company hired to help with the study may send you automated emails reminding you to provide information on your alcohol consumption during



the past 24 hours. These emails will be sent to the email address that you provide to your study site. To discontinue receiving these messages, please contact your study site.

Please note that depending on the settings used on your mobile device, messages received through the mobile application, text message or email may appear on your mobile phone as soon as they are received, even when the phone is locked. These messages could therefore be seen and read by others who are near your phone when the messages are received.

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6 years. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety concerns.

**[THE NEXT PARAGRAPH IS ONLY FOR SITES THAT WILL FOLLOW-UP THEIR PARTICIPANTS AFTER MACH15 ENDS]**. You can also agree to allow the study staff to review your medical records and information through national databases at the Social Security Administration, Medicare and Medicaid, the National Center for Health Statistics, the United States Renal Data System, and the Veterans Administration after MACH15 ends. This would include your hospitalizations for heart disease, kidney disease, falls and brain disorders, and other related diseases. If you have moved to an assisted living facility or a nursing home, the study will collect this information too. All of these records will be kept confidential. When we are using national databases to collect information, no one from MACH15 will contact you or your family for any further information. The review of your medical records and data base searches would begin after your last study visit at INSERT SITE INFORMATION and may last until 2032.

## WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. There are risks of harm or discomfort associated with the intervention and with study assessments. Because researchers do not know which arm of the study will experience better health outcomes, it is possible that you could be randomized to the arm of the study that performs either better or worse than the other arm.

A Data and Safety Monitoring Committee, an independent group of experts, will be reviewing the data and monitor participant safety throughout this study.

### **Alcohol (if in alcohol group):**

Alcohol can have many risks, even with one drink per day. These include:

More Common: Alcohol is an addictive substance. Alcohol should never be used by people who have



or have had problems controlling their alcohol use. It may interfere with the ability to drive or operate dangerous or delicate machinery, including cars, boats, and other vehicles, and should never be used before such activities. Alcohol may cause sedation, disturb sleep, and impair balance. In some people, alcohol causes severe flushing. This can also occur if alcohol is taken with certain medications. You should check with your doctor or the site staff to determine if you are taking any medications that should not be used with alcohol. Alcohol can increase the calming effects of any medication that causes drowsiness, including cough and cold medicines and drugs for anxiety and depression. Alcohol can raise levels of triglycerides, a type of fat in the blood. In people with chronic liver disease, alcohol can cause liver damage.

Less Common: Each alcoholic beverage contains ~100 calories and can cause weight gain. Alcohol can increase or decrease blood pressure. Alcohol can trigger irregular heartbeat (atrial arrhythmia).

Rare: One drink per day can slightly raise the risk of breast cancer in some women, especially those who have a family history of breast cancer. This amount of alcohol may also raise the risk of mouth and esophagus cancer. It is not possible, however, to predict how alcohol will affect the risk for these cancers in any one person. In individuals with unrecognized liver disease, one drink per day can increase the risk of cirrhosis (irreversible liver damage). In addition, it is possible that some people with no prior history of alcoholism could develop problem drinking even late in life. Complications of problem drinking are numerous, severe, and often irreversible and include trauma, suicide, cancer of many organs (including complete digestive tract, liver and breast), injury to the heart and other muscles, brain and nerve damage, infections, liver damage and cirrhosis, high blood pressure, stroke, and damage to one's relationships with family, friends, and work.

#### **Blood draws:**

This study requires that blood be drawn from a vein in your arm several times during the study. You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions.

#### **Other study procedures:**

Some aspects of this study may make you feel uncomfortable. You will be asked to drink or abstain from drinking alcohol daily, even while on vacation or travelling. We also ask you to provide information that you may consider confidential or private. Some of the questions may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the visit.

#### **Reproductive Risks:**

Due to the risks and potential harm to an unborn fetus, women who are interested in participating in this study must be postmenopausal.



## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in MACH15, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future.

### **Regular testing of blood lipids, glucose status and liver enzymes:**

At each visit blood will be drawn to test your lipid levels and glucose status. Also liver enzyme concentration will be measured which can be used to estimate if your liver is functioning well. Regular testing of your lipid and glucose levels may make you more aware of changes in your health status.

### **Advice on healthy lifestyle:**

As part of this study, you will receive general advice on a healthy lifestyle. You will be more aware of the importance of a healthy diet and physical activity which may be positive for your health and wellbeing.

## WHAT OTHER CHOICES ARE THERE?

Taking part in this study is voluntary. Instead of being in this study, the alternative is not to participate. We recommend that you discuss your options with the investigator and your doctor so that you can make a well informed decision about participating in this study.

## WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

## WILL I BE PAID FOR PARTICIPATING?

**INSERT SITE SPECIFIC INFORMATION AS APPLICABLE**

### **FOR SITES THAT ARE ABLE TO PAY FOR PARTICIPATION USE THIS LANGUAGE:**

You will be paid XXX for each study visit that you complete. If you withdraw for any reason from the study before completion you will not be paid for visits that you did not complete. In addition, participants randomized to the alcohol group will be reimbursed XXX/month for the purchase of their alcoholic beverage and participants randomized to the non-alcohol group will be reimbursed XXX/month for the purchase of a non-alcoholic beverage.

### **FOR SITES THAT ARE NOT PAYING THEIR PARTICIPANTS USE THIS LANGUAGE:**

You will not be paid for participating in this study. You will be reimbursed for incurred travel expenses up to XXX per visit. If you are randomized to the alcohol group, you will be reimbursed XXX/month for the purchase of your alcoholic beverage. If you are randomized to the non-alcohol group, you will be reimbursed XXX/month for the purchase of a non-alcoholic beverage.





To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still take part in this study but you will not be paid.

## WHO IS SPONSORING THIS STUDY?

The study is funded and overseen by the National Institute on Alcohol Abuse and Alcoholism, one of the National Institutes of Health (NIH). NIAAA itself has received partial contributions from the Foundation for NIH, an independent charity that raises private funds to support the mission of the NIH. FNIH has received donations for this trial from companies that produce alcohol-containing beverages. These companies and the FNIH had no role in the design of the study, have no role in its conduct, and will have no role in any study publications.

## WILL MY RESEARCH RECORDS BE CONFIDENTIAL?

Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Your study records including medical data and participant information may be provided to Federal and other Regulatory (Health) Authorities upon request. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction. The results of this research study may be presented at scientific or medical meetings. The results may also be published in scientific journals. If this study results in publications or presentations, you will not be directly identified.

If you agree, we can send copies of your test results to your doctor. You can still participate in this study even if you do not wish to have any of your medical information sent to your doctor.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of intent to harm yourself, if required by state or local law.





## HOW WILL MY HEALTH INFORMATION, RESEARCH DATA, BIOLOGICAL SAMPLES BE PROCESSED, TRANSFERRED AND STORED?

***INSERT SITE SPECIFIC INFORMATION WHERE APPROPRIATE***

### **Health Information:**

All information we collect from you is considered Protected Health Information. For this study this includes but is not limited to, things like your name, address, telephone number, social security number, date of birth, and medical data including laboratory results. This information will be collected from various sources, including your study visits, your medical records, and the mobile application used in the study.

All Protected Health Information collected during this study will be treated as strictly confidential. We will make every effort to keep your Protected Health Information private by assigning you a participant ID under which all your records will be stored. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. If you choose to use the mobile application or receive the text messages or emails that are described earlier in this form, your participant ID, along with your name and other personal information about you (e.g., your phone number and email address), will be provided to the company providing these services to permit that company to send you these communications. This company is called MyOwnMed, though the study may choose to use a different company to provide these services in the future.

Your Protected Health Information will be coded with a participant ID before it leaves the clinical site. Your coded Protected Health Information, including information collected through the mobile application, will be provided to Wake Forest University Health Sciences for storage and processing during and after the study. Wake Forest University Health Sciences may share your coded Protected Health Information during and after the study with other investigators, staff, institutions, and companies involved in this study, including but not limited to the following entities:

- Companies providing services to the study. This includes the company providing the mobile application and sending text messages and emails for the study.
- Beth Israel Deaconess Medical Center, which is administering the study, the Harvard School of Public Health, which is providing statistical analysis services for the study, and the National Institutes of Health, which is sponsoring the study.

In addition, Wake Forest University Health Sciences may share your coded Protected Health Information with investigators, staff and institutes, including those not involved in the study, that apply to receive information from the study for further research.

Your Protected Health Information including your study record containing your name or other directly



identifying information, may be reviewed by authorized representatives of the sponsor; investigators at other sites who are assisting with the research; central laboratories or analysis centers; the Institutional Review Board; the Ethics Committee; the Data and Safety Monitoring Board; representatives of Wake Forest University Health Sciences and Julius Clinical, which act as coordinating centers and perform monitoring activities for the study; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries. Your study record and medical record may be reviewed by them only in connection with carrying out their obligations relating to this study.

Your Protected Health Information may be disclosed if required by law. If required by law or court order, we might have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others.

Some of the individuals and entities described above that receive your Protected Health Information or your coded Protected Health Information may not be required to comply with federal or state privacy rules and may re-disclose your information in ways not discussed in this form.

Any information collected from you in this study that is maintained in the research records will be kept for at least three years after the end of the study or longer depending on local laws and regulations. Any research information entered into your medical record will be kept for as long as your medical record is kept by this clinical site.

By signing this form you give us and Wake Forest University Health Sciences permission to use and disclose your Protected Health Information for this study. You do not have to give this permission, but if you do not give it, you will not be able to participate in this study. If you decide not to give this permission, your decision will not affect your health care outside of the study, the payment for your health care, or any other benefit to which you are entitled.

This permission does not expire unless you take away your permission. You can tell INSERT SITE PRINCIPAL INVESTIGATOR that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

**Principal Investigator Name**

**Mailing Address**

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected will be considered results that are retained to preserve the integrity of the research.



A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The restrictions on uses of Protected Health Information described in this form do not apply to de-identified data, which are data from which readily identifying personal information about you, including your name, address, and phone number have been removed and replaced with a code number which is different from your participant ID. Your de-identified data may be used and shared for other purposes that are not described in this form.

***IF APPLICABLE, INCLUDE THIS LANGUAGE***

If you choose to participate in this study, your medical record at *INSERT SITE SPECIFIC INFORMATION* will indicate that you are enrolled in this research study. Information about the research may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this site, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

***IF APPLICABLE, INCLUDE THIS LANGUAGE***

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of *INSERT SITE SPECIFIC INFORMATION*. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

**Research Data Archive:**

De-identified data from this study may be submitted to a central data archive in the United States (US) called the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the US National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all readily identifying personal information about research participants such as name, address, and phone number is removed and replaced with a code number which is different from your participant ID. With an easier way to share information, researchers hope to learn new and important things about illnesses more quickly than before.

During and after the study, the MACH15 researchers may send de-identified information about your health and behavior and in some cases, your genetic information (if available), to NDA. Other researchers can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health information will look at every request carefully to minimize risks to your privacy.



You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments. NIMH will also report to US Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at <http://data-archive.nimh.gov>.

**Blood sample for DNA (optional):**

If you agree, some of the blood sample that will be obtained at the baseline visit may be used in future studies to study your genes (also called DNA) in order to understand heart and other diseases. Therefore, the coded samples will be stored at Brigham and Women's Hospital/Harvard Cohorts Biorepository (Boston, MA) for an indefinite period. Data generated from the samples will be kept by Wake Forest University Health Sciences to preserve the integrity of analyses which have been performed. Your gene information will not be given to you or your doctor and will not be placed in your medical record.

**Blood, urine, and hair sample collection for future research:**

Some of the blood, urine, and hair samples may be used in future research to learn more about heart and other diseases related or potentially related to alcohol. Your samples will be coded. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the information that links the code with your identifiable information. The coded samples will be stored at Brigham and Women's Hospital/Harvard Cohorts Biorepository (Boston, MA) and *INSERT SITE INFORMATION HERE IF STORING SAMPLES LOCALLY*. Only researchers that have their research proposal approved by the MACH15 Steering Committee and Institutional Review Board (IRB)/Ethics Committee (EC) may use your coded sample.

The research that may be performed with your stored blood or urine sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your samples will not be given to you or your doctor. The results will not be put in your medical record.

Your stored blood and urine sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.



In the future, researchers may like to know more about your health. While future researchers may be given reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future by the Principal Investigator or other researchers.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety concerns. The investigators also have the right to stop your participation in the study at any time. This could be because you had an unexpected reaction, did not follow instructions, the drinking guidelines provided, or because the entire study has been stopped.

You will be given any new information gained during the study that might affect your health, welfare, or willingness to stay in MACH15. If you agree, we will send the results of your laboratory tests to your doctor.

## WHAT HAPPENS IF I EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

**EACH SITE MUST USE THE LANGUAGE PROVIDED BY THEIR SPECIFIC INSTITUTION**

Should you experience a physical injury or illness as a direct result of your participation in this study, INSERT SITE SPECIFIC INFORMATION maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of XXXX. INSERT SITE SPECIFIC INFORMATION holds the insurance policy for this coverage. It provides a maximum of XXXX coverage for each claim and is limited to a total of XXXX for all claims in any one year. The INSERT SITE SPECIFIC INFORMATION do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the INSERT SITE SPECIFIC INFORMATION.

You do not give up any legal rights as a research participant by signing this informed consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call PI's Name at telephone number (also include after hours number).



### WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, if you feel that your alcohol consumption is excessive or problematic, or in the event of a research-related injury, contact the study investigator, Name at telephone number *(also include after hours number)*.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at insert telephone number.

You will be given a copy of this signed informed consent form.

### PARTICIPANT'S STATEMENT OF CONSENT FOR MACH15

I have had the opportunity and sufficient time to review the study information, ask my investigator questions about this study, and my questions have been answered. I understand the conditions and procedures, and I have been informed of the possible risks and benefits from taking part in this study.

Participant Name (Printed): \_\_\_\_\_

Participant Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ (24 hour clock)

Person Obtaining Consent (Printed): \_\_\_\_\_

Signature of Person Obtaining Consent: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ (24 hour clock)



**Please review each question below and place your initials in the space corresponding to your answer.**

**AGREEMENT FOR REPORTING MEDICAL RESULTS TO DOCTOR**

Do you request that we send important medical findings from your study tests/exams to your doctor?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO

**AGREEMENT TO PARTICIPATE IN ONLINE QUESTIONNAIRES**

Are you willing to complete online questionnaires about your physical activity and the foods that you eat?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO

**AGREEMENT FOR CONTACT FOR FUTURE RESEARCH STUDIES**

Are you willing to be contacted for future research studies?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO

**AGREEMENT FOR COLLECTION AND STORAGE OF BLOOD/URINE/HAIR FOR FUTURE RESEARCH STUDIES**

Are you willing to provide blood to be stored for use in future research?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO

Are you willing to provide urine to be stored for use in future research?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO

Are you willing to provide hair to be stored for use in future research?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO

**AGREEMENT TO PARTICIPATE IN GENETIC STUDIES**





Do you agree to allow your genetic sample (DNA) to be used in future research?

\_\_\_\_\_ YES

\_\_\_\_\_ NO

**AGREEMENT FOR LONG TERM FOLLOW-UP**

I agree to allow the MACH15 Data and Clinical Coordinating Center located at Wake Forest University, or its designee, to review and collect data on my medical records for specific study information through national databases until 2032.

\_\_\_\_\_ YES

\_\_\_\_\_ NO